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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,901	03/09/2001	James M. Zavislan	ML-0486US	6601

7590 11/17/2004
Kenneth J LuKacher
South Winton Court
Suite 304
3136 Winton Road South
Rochester, NY 14623

EXAMINER

FRANKLIN, JAMARA ALZAIDA

ART UNIT	PAPER NUMBER
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2876

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/786,901

Applicant(s)

ZAVISLAN ET AL.

Examiner

Jamara A. Franklin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19-22, 28, 29, and 32 is/are allowed.
- 6) ☒ Claim(s) 1, 15, 16, 24, 26, 31 and 33 is/are rejected.
- 7) ☒ Claim(s) 2-14, 17, 18, 23, 25, 27 and 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgment is made of the response received on 8/25/04. Claims 1-33 are currently pending.

Claim Objections

1. Claims 8 and 28 are objected to because of the following informalities:

in claim 8, line 2, insert --and-- between "shell" and "said"; and

in claim 28, line 2, substitute "capable of producing" with --which produces--.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 15, 16, 24, 26, 31, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Devlin et al. (US 5,383,472) (hereinafter referred to as 'Devlin').

Devlin teaches a system for imaging biopsy tissue which comprises means for encapsulating an excised tissue specimen in compression in a transparent holder, and means for scanning said holder and providing an image of the tissue specimen suitable for pathological examination (col. 5, lines 12-18 and col. 6, lines 29-51); and

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the system further comprising means for providing alignment of said specimen with an indicia or fiducial mark on said holder, and means for referencing said image with respect to said mark (see figure 2).

Allowable Subject Matter

4. Claims 19-22, 28, 29, and 32 are allowed.

5. Claims 2-14, 17, 18, 23, 25, 27, and 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record fails to teach, or fairly suggest either alone or in combination thereof, a method for imaging of surgical biopsies which has the step of scanning the cassette to provide at least one image for pathological examination of a specimen and a system for imaging biopsy tissue wherein the imaging system has a stage in which an encapsulated specimen is moved during imaging. No stage is suggested in the Devlin invention.

Also, the prior art of record fails to teach or fairly suggest the scanning feature operative in accordance with one of confocal microscopy, optical coherence tomography, and two-photon microscopy.

Also, the prior art of record fails to teach or fairly suggest that the holder is a trocar.

Response to Arguments

7. Applicant's arguments, see pages 6 and 7, filed 8/25/04, with respect to claims 2-14, 17, 18, 23, 25, 27, and 30 have been fully considered and are persuasive. The rejection of the preceding claims has been withdrawn.

8. Applicant's arguments filed 8/25/04 with respect to claims 1, 24, and 26 have been fully considered but they are not persuasive.

The examiner submits that independent claims 1 and 24 do not explicitly state that the cassette/holder in which the specimen is contained is scanned (as indicated in independent claim 19). Instead, independent claims 1 and 24 are interpreted as the tissue specimen, itself, is suitable for pathological examination, and is thereby read upon by the Devlin invention.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Lary et al. (US 5,156,150) teach a method of use of specimen.

Russell (US 5,383,234) teaches a radiographic system and a method for using the system for radiographic examination of tissue specimens.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

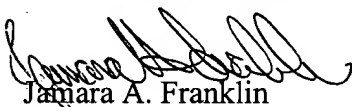
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jamara A. Franklin whose telephone number is (571) 272-2389. The examiner can normally be reached on Monday through Friday 8:00am to 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Lee can be reached on (571) 272-2398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jamara A. Franklin

Examiner

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JAF

November 15, 2004



DIANE I. LEE
PRIMARY EXAMINER